

SOUTH AFRICAN PAEDIATRIC SURGICAL OUTCOMES STUDY 2

IMPORTANT PATIENT INFORMATION

A research study is being conducted at (NAME) Hospital.

The research is being done by (Lead Investigator name) from 05 September to 28 July 2023.

What is this research project all about?

When children come to hospital for an operation the nurses or doctors do a blood test. Sometimes one of the results on the blood test is lower than normal. This is called anaemia and doctors know if children have anaemia they may have more problems when they have an operation. Doctors think that it will help if they can give children medicine before they have their operation to make their blood test better.

Why have I been invited to take part in this research project?

Because you are going to have an operation.

What will happen to me in this study?

The nurse or the doctor is going to do a finger-prick test to check for anaemia. If the test result on the finger-prick is lower than normal, then the nurse or doctors will do a blood test and you will be given an iron supplement to take at home every day before surgery.

Will this study affect my care while I am in hospital?

No. Your care will not change while you are in hospital.

Will my name or any personal details be recorded in this study?

No. Your name and personal details will not be recorded as part of this study. All information from the notes will be kept strictly confidential.

Are there any risks or benefits associated with this study?

Taking a blood sample may be sore and may cause a bruise.

Some children may become constipated, nauseous, or have a sore tummy when they take the iron supplement.

May I withdraw from this study?

Every patient has the right to withdraw from this study.

If you have questions about your rights or welfare as a research participant, please contact the UCT Faculty of Health Sciences Human Research Ethics Committee on +27 (0)21 406 6338.

Appendix D – SAPSOS-2 Patient Information Leaflet

SAPSOS-2 Research Study

Information for parents and guardians of children

This booklet explains what to expect when your child takes iron medicine as part of this study

If you are worried or want to ask any questions about the medicine or the study then please feel free to send an SMS or WhatsApp message to the research assistant (XXX, cell phone XXX), and they will call you back. The research assistant will also call you once a week to ask you if your child has managed to take their medication, or if there were any problems with taking the medication.

It is very important that the iron medicine is stored in a safe place that your child, or other children cannot reach. Iron overdose can be very dangerous. **If you are worried a child has taken an iron overdose please contact the Poison Information Helpline 24/7 emergency number 0861 555 777 immediately.**

Anaemia

You have been approached because your child may be able to be a part of a research study on anaemia. The doctors that are part of this study are trying to find out if they can test children for anaemia in the hospital clinic and then treat the anaemia before the child has their operation

What is Anaemia?

Anaemia means that the haemoglobin measured on a blood test is lower than normal. Anaemia in children having surgery is very common.

How did the Doctor find out my child has anaemia?

The blood test at the hospital clinic showed that your child has anaemia.

What causes anaemia?

There are different types of anaemia, but the commonest cause of anaemia is not enough iron in the body. This is known as iron deficiency anaemia.

Why does my child have anaemia?

The doctors do not know for certain why your child has anaemia, but they have done blood tests to see whether your child has anaemia because of too little iron.

Why would my child have too little iron?

This can happen three ways

- 1) Not enough food with iron
- 2) The body does not absorb iron
- 3) The body is losing iron eg. bleeding

Can anaemia be treated?

Yes. If the anaemia is caused by a not enough iron, giving iron medication will help.

Yes. If your child has worms this can cause anaemia. Treating your child with deworming medicine every 6 months can help.

When your child is admitted to hospital for surgery the doctors will be able to tell you if the test results in the hospital clinic showed that your child does not have enough iron.

If the anaemia is not because of too little iron, the iron medication will probably not help, but it is still safe for your child to take the medicine.

Can anything good happen to my child if they take the iron?

Doctors think that it will help if they can give children medicine before they have their operation to make the haemoglobin on the blood test better. This will also help them to know how best to treat other children.

At the moment the doctors only check if your child has anaemia the day before, or on the day of the operation. This means there is no time to treat the anaemia before your child has the operation.

Because you have agreed for your child to be part of this study, the doctors have already tested your child for anaemia.

This means the doctors can already try to treat the anaemia by giving your children iron syrup or tablets to drink every day before your child has their operation.

Can anything bad happen to my child if they take the iron?

Your child's poo may be black or darker in colour than usual and that this is normal/expected.

Some children may feel a bit nauseous or have tummy cramps, but this should settle within a week or so.

Constipation

Constipation can be a problem while your child takes this medicine. Fresh fruit, vegetables and high fibre breads and cereals are good foods to help avoid constipation. Make sure your child drinks lots of fluids, like fruit juices, while on the iron medication

How do I give my child the medicine?

Try to give the medicine at same time each day to help you remember to give it.

Use a spoon or a syringe.

Try to give on an empty stomach.

What do I do if my child refuses to take the medicine?

You can mix the iron in other foods such as formula milk, juice, cereal etc

Do not mix it with cow's milk as dairy stops the body absorbing iron absorption; try to wait 2 hours after giving milk before giving the iron

Try to avoid the medicine touching the teeth too much, as it can stain teeth; aim for back of mouth with spoon or syringe, or mix with water or juice. Any staining can be removed by brushing with toothpaste or sodium bicarbonate

When do I start giving my child the medicine?

Your child should take the medicine every day, starting from today.

What will happen when my child is admitted to the hospital for their surgery?

Everything will happen just like it normally would.

When your child is admitted to hospital for their surgery, as part of their routine care, a finger-prick or blood sample will be taken to recheck the haemoglobin. Doctors often need to know the result before the operation, but the doctors will also do the blood test when your child is asleep during the operation if it is safe to do so.

Will I find out the results of the blood tests done as part of this study?

The doctor looking after your child in hospital will be able to tell you whether your child's haemoglobin is better, or whether your child needs further tests or medicine for anaemia.

What happens after the surgery?

If your child still has anaemia, the doctor will tell you if your child needs to have any more tests or take any more medication.